

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

*DMF*

Display Date	<i>2-01-01</i>
Publication Date	<i>2-02-01</i>
Certifier	<i>[Signature]</i>

**Antiviral Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Antiviral Drugs Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on February 27, 2001, 9 a.m. to 5:30 p.m.

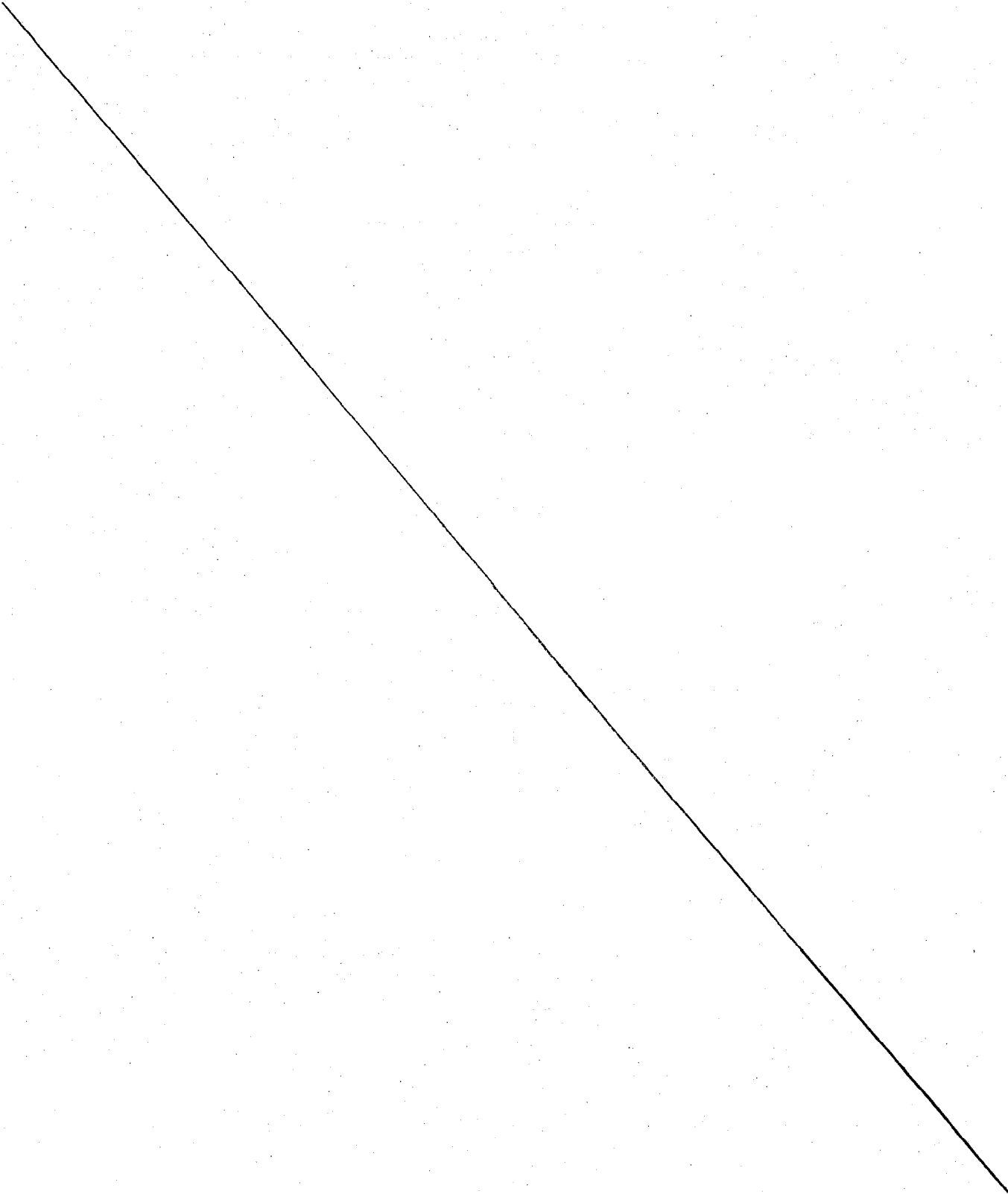
*Location:* Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person:* Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committee will discuss new drug application (NDA) 21-304, valganciclovir hydrochloride tablets, 450mg, Syntex (U.S.A.) LLC, proposed for treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS).

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 20, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make

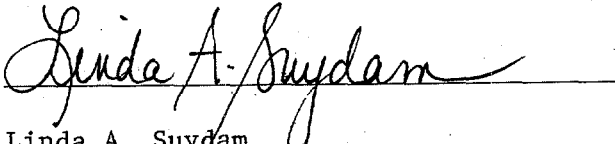
formal oral presentations should notify the contact person before February 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.




Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 1/18/01  
January 18, 2001

  
Linda A. Suydam  
Senior Associate Commissioner

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL



[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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